

### **REMARKS**

Claims 18-34 are currently pending in the above-identified application. Claims 1-17 have been canceled. Claims 18 and 26 have been amended. Claims 33-34 have been added. Claims 18 and 26 are the independent claims.

Claims 18-20, and 23-25 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,330,497 to Freitas et al. Claims 18-20, and 26-32 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,830,125 to Scribner et al. Claims 26-32 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-16 of U.S. Patent No. 6,743,207. Claims 21 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Applicants thank the Examiner for the indication that claims 21-22 contain patentable subject matter.

### **The Claims, As Amended, Are Patentably Distinct Over Freitas and Scribner**

Claims 18-20, and 23-25 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,330,497 to Freitas et al. Claims 18-20, and 26-32 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,830,125 to Scribner et al. The applicants submit that the claims are patentably distinct from Freitas and Scribner for several reasons.

First, applicants submit that the claims are patentably distinct because neither reference discloses or suggests an overtube “adapted for insertion through a tissue wall,” as recited in independent claim 18. Similarly, Scribner does not disclose or suggest the step of “inserting an overtube ... through the body wall,” as recited in independent method claim 26. In the applicants’ invention as claimed in amended apparatus claim 18, a medical device insertion apparatus comprises a trocar, an access tube, and an overtube to fit over the access tube, “wherein the overtube is adapted for insertion through a tissue wall.” The access tube has a retention portion at a distal end that is reconfigurable between a reduced lateral extent and an increased lateral extent. The overtube moves over the access tube and penetrates through the

body wall, for example, the overtube is adapted for insertion through a patient's gastric wall into the gastric cavity. *See, e.g.*, Application, Figs. 4 & 7, ¶¶ 28-29.

Freitas fails to disclose or suggest an overtube adapted for insertion through tissue. Freitas shows a locking trocar sleeve 10 having an outer plastic sleeve 30 and a dense foam rubber stop 72 that can be slid down sleeve 30 to contact the outer surface 74 of the abdominal wall 18. *See* Freitas, col. 4:40-46; Fig. 1. In an alternative version, a stop 154 has ridges that engage mating elements on the outer sleeve 102, which allow the stop to “be quickly pushed against the outer surface of the patient's skin.” *Id.*, col. 7:9-14; Fig. 8. Accordingly, the stop in Freitas rests against the outer skin surface and is not an overtube adapted for insertion through a tissue wall.

Likewise, Scribner fails to disclose or suggest an overtube adapted for insertion through a tissue wall or body wall. Scribner regards “a catheter introducer capable of assisting in threading suture material through a tissue wall.” *See* Scribner, Abstract. In the device of Scribner, the positioning member 50 does not penetrate through the arterial tissue wall. Rather, the “apparatus 10 is further inserted into the incision 14 until the artery wall 12 is positioned between the expandable portion 38 of the second tube 30 and the positioning member 50.” *Id.* col. 10:66 – col. 11:2; Fig. 2B. In other words, the positioning member 50 is not inserted through a tissue wall. Scribner is directed to suturing incisions of arterial walls, which can lead to hematoma and other complications, thereby minimizing the incision in the tissue wall. Thus, Scribner does not disclose, and teaches away from, the insertion of an overtube with its larger diameter through the tissue wall.

The Applicants respectfully submit that neither Freitas nor Scribner discloses or suggests an overtube as claimed. The stops 72, 154 of Freitas are not an overtube as claimed. It is not adapted for insertion through a tissue wall to penetrate the body. The positioning member 50 of Scribner has similar deficiencies.

Second, the Applicants submit that the claims are patentably distinct from Freitas and Scribner because independent claim 18 has been amended to incorporate some of the limitations of dependent claim 21, which was not rejected in the Office Action, to obviate the §102 rejection. Accordingly, amended claim 18 is patentably distinct because neither reference

discloses a slotted overtube "...wherein, when the retention portion of the second sheath is in the second configuration of increased lateral extent, the retention portion is receivable within the at least one slot." The Applicants respectfully submit that neither the stop of Freitas nor the positioning member of Scribner comprise at least one slot to receive the expanded retention portion.

Third, for the same reasons discussed above, the Applicants submit that method claim 26 is patentably distinct from Scribner because Scribner does not disclose the step of "advancing the overtube over the retention portion." The positioning member 50 of Scribner does not advance over expandable portion 38. Rather, the "artery wall 12 is positioned between the expandable portion 38 of the second tube 30 and the positioning member 50." See Scribner, col. 10:66 – col. 11:2; Fig. 2B.

Accordingly, for all the above reasons, applicants respectfully submit that the claims are patentably distinct over Freitas and Scribner.

#### **Non-Statutory Double Patenting Rejection**

Claims 26-32 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-16 of U.S. Patent No. 6,743,207. Attached please find a Terminal Disclaimer, disclaiming the terminal part of the statutory term of any patent granted hereon which would extend beyond the expiration date of the full statutory term of U.S. Patent No. 6,743,207. Also enclosed is an Assignment document setting forth the change of name of Scimed Life Systems, Inc. to Boston Scientific Scimed, Inc., the owner of the U.S. Patent No. 6,743,207 and the current application. The documentation of the change of name has been filed for recordation with respect to U.S. Patent No. 6,743,207 as well. The Terminal Disclaimer obviates the non-statutory double patenting rejection.

#### **Claims 33-34 are New**

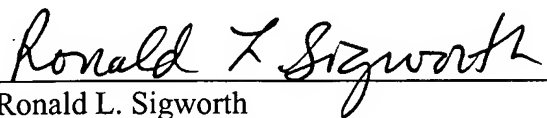
Claims 33 and 34 are new dependent claims that have been added that depend from independent claim 18. Support for these new claims can be found at least in paragraphs 28 and 29 of the application. Since claim 18 is believed to be in condition for allowance for the reasons

stated above, applicants submits that claims 33 and 34 are patentable over the cited references.  
Claims 33 and 34 do not raise any new issues or subject matter.

The Office is authorized to charge any underpayment or credit any overpayment to  
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Respectfully submitted,

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